IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. 09/927,914 Confirmation No. 5180

Applicant Timothy P. Tully *et al*.

Filed 10 August 2001

TC/Art Unit 1617

Examiner Yong Soo Chong

Docket No. 21RE-137270

Customer No. 68850

APPLICANT'S REPLY TO EXAMINER'S SUMMARY OF PERSONAL INTERVIEW OF NOVEMBER 18, 2010

Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

MAIL STOP AF

Applicant has reviewed the Examiner Summary, mailed November 22, 2010 ("Summary"), of the Personal Interview held at the USPTO on November 18, 2010. Applicant thanks Examiner Yong Chong for the courtesy of the interview and also thanks Supervising Examiner Sreeni Padmanabhan and Quality Assurance Specialist Kathleen Bragdon for their attendance at the interview.

The Examiner provides the following description of the "Substance of the Interview."

The rejections of record were discussed. Both Applicant and Examiner gave their own interpretation of the cited prior art and the claims.

Summary at p. 2.

Applicant respectfully makes the following points in reply: First, Applicant did not just merely give its *interpretation* of the prior art at the Interview. The arguments made by Applicant at the Interview, and particularly those regarding *Christensen*, were based upon and included discussion of the extensive evidence previously submitted in this case. This evidence includes numerous scientific articles submitted by Applicant in

the August 8, 2009 Supplemental Reply showing that the action of TNF is limited to a narrow therapeutic window in after the onset of stroke, and moreover, that administering an anti-inflammatory inhibitor beyond the acute phase is contraindicated by studies showing a beneficial role for TNF, and the inflammatory response generally, in protecting neurons and promoting plasticity during stroke recovery. This evidence also includes the stroke references incorporated into the specification and discussed in detail in the August 8, 2009 Supplemental Reply. These references confirm that stroke rehabilitation is temporally distinct from the acute phase, and they also show that cognitive training protocols are *active* interventions – not the *passive* exercises that the Examiner improperly cites in *Merck*.

Second, Applicant agrees with the Examiner that he gave his own interpretation of the prior art, but further emphasize – and did so at the interview – that the Examiner's interpretation relies on conjecture and opinion and lacks an evidentiary basis in the art. For example, the Examiner has repeatedly asserted that *Christensen* teaches the administration of a PDE4 inhibitor to a stroke patient at all stages in treatment, which includes rehabilitation. But as Applicant has repeatedly pointed out, this assertion relies entirely on claim 1, which recites neither a "stroke patient" nor "rehabilitation" and ignores contradictory disclosures in *Christensen*, therefore failing to consider the reference as a whole.

In summary, Applicant respectfully asserts – as it has repeatedly in the past – that the Examiner has not provided any substantive or proper rationale to support the rejections of the instant application. In doing so, the Examiner has improperly disregarded the strong evidentiary support that Applicant has provided to support its position. Compounding this issue is the USPTO's failure to correct (until October 2010) the improper withdrawal of claims 2, 9-10, 13, and 80-85 more than seven years ago – on May 7, 2003. Moreover, the Examiner sought to obfuscate the relevant issues at the Interview by raising new arguments and improperly threatening to impose

additional rejections. These actions have improperly delayed allowance of the instant application by the USPTO. They have also forced the Applicant into unnecessarily protracted prosecution – despite its continued and reasonable efforts to conclude examination.

Respectfully submitted,

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Date: December 22, 2010

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